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10/821,718	04/09/2004	Clyde L. Schultz	RH01.701US	1509
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			EXAMINER MAHYERA, TRISTAN J	
			ART UNIT 4173	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/821,718

Applicant(s)

SCHULTZ, CLYDE L.

Examiner

Tristan J. Mahyera

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) ~~4-16~~<sup>1-19</sup> is/are pending in the application. 15-19
- 4a) Of the above claim(s) ~~15-19~~ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-16 in the reply filed on 08/31/2007 is acknowledged.

Claims 15 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 17-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-14 are examined on the merits.

### ***Specification***

Claims 3 and 3' are objected to because of the following informalities: Two instant claims numbered "3" are used. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112 1<sup>st</sup>***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for amelioration and stabilization in the treatment of posterior segment disease, does not reasonably provide enablement for a cure or prevention of posterior segment diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. As used herein, the cure or prevention of a disease is viewed as meaning that the disease can be absolutely cured or 100% prevented.

Claims 2-14 are rejected at least as depending from a rejected claim and not clarifying this issue.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988).

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art

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and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

**The breadth of the claims/The nature of the invention:** Rejected claim 1 is drawn toward a polymeric hydrogel comprising a drug wherein the drug is capable of treating posterior segment disease. The definition of treatment given by the instant specification is "...managing a patient with the intent that a prevention, cure, stabilization, or amelioration of the symptoms will result." See specification page 3 lines 14-15. The invention is complex in that it is directed toward amelioration and stabilization of posterior segment diseases by application of a drug to the posterior segment of the eye through the use of a hydrogel. Posterior segment diseases include retinal detachment, diabetic retinopathy, macular degeneration, proliferative vitreoretinopathy, endophthalmitis, retinopathy of prematurity, posterior segment trauma, intraocular lens-related posterior segment complications, retinal degenerations, AIDS-related retinitis, posterior segment uveitis, and systemic diseases with retinal manifestations. The amelioration or stabilization of any of the above-mentioned diseases is a complex process. However, the complexity is exacerbated by the breadth of the definition of treatment, which further includes both the prevention and cure of all posterior segment diseases.

**Guidance of the specification/Existence of working examples:** The specific teachings of the specification are devoid of examples disclosing the prevention or cure of any posterior segment disease. Furthermore, the specification does not disclose any

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examples where a specific posterior segment disease is treated. The lack of guidance and working examples in the specification is indicative of the excess experimentation necessary to practice the invention in that scope claimed. In particular, while experimentation is required to create a hydrogel that ameliorates/stabilizes a posterior segment disease, the amount of experimentation necessary to cure/prevent a posterior segment disease, if possible, especially without any working examples or guidance is excessive. No evidence is provided in the specification that leads to the conclusion that any of the disclosed posterior segment diseases are absolutely curable or preventable by the claimed compositions.

**The state of the prior art/Predictability of the art:** At the time of applicants' invention (4/09/2003) the level of skill in the art of amelioration or stabilization of posterior segments diseases by the use of a polymeric hydrogel comprising a drug was unpredictable and underdeveloped. COLTHURST states that the majority of posterior segment diseases are treated by surgery or laser photocoagulation and only a minority feature drug therapy as the primary method of treatment. See p651 section 4.1. The most common method of drug delivery to the posterior segment is topical and this is unsuitable for posterior segment drug therapy because a drug would need to penetrate the cornea, pass through the anterior segment against the flow of aqueous humour and diffuse throughout the vitreous, thus only a subtherapeutic dose may reach the target site. See p652 section 4.4. The specific use of hydrogels has not demonstrated an increase in predictability as fragmentation of explants can occur with an associated risk of complications. See p653 section 6.3. An additional reaction to hydrogels has

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occurred such as a foreign body giant cell granulomatous against the hydrogel. See p653 section 4.4. The prior art of record does not teach curing or preventing posterior segment diseases, and as shown in COLHURST the predictability of using hydrogels is low in comparison to better known or more widely practiced methods of ameliorating or stabilizing posterior segment diseases.

**The quantity of experimentation necessary:**

In order to practice the claimed invention one of ordinary skill in the art would have to first envision a drug that can pass the blood-retinal or blood-aqueous barrier of the eye. This drug would need to be capable of being incorporated into a specific hydrogel composition. The design of the hydrogel-drug interaction would need to be commensurate with either an immediate or controlled release function to allow the release of an appropriate therapeutic amount. Once released, the drug must further penetrate the cornea, pass through the anterior segment against the flow of aqueous humour, and diffuse throughout the vitreous to reach the posterior segment. While possible to stabilize or ameliorate diseases, the ability to cure or prevent diseases requires knowledge not present in the art due both to the physical restraints on the drug delivery through the ocular segments and the inability to absolutely cure or prevent any posterior segment diseases as demonstrated by the prior art of record.

Thus, it would require undue, unpredictable experimentation for one of skill in the art to make and use the claimed invention commensurate in scope with the rejected claim. Therefore, the claimed invention of a polymeric hydrogel comprising a drug

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capable of curing or preventing posterior segment diseases is not considered fully enabled by the instant specification.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 5, 6, 9, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by SCHULTZ et al. (US 5,723,131).

SCHULTZ teaches the use of a polymeric hydrogel comprising desferrioxamine as the medicinal agent to kill or inhibit the growth of bacteria. See column 1 lines 11-16. Desferrioxamine controls bacteria such as *Pseudomonas aeruginosa* and *Staphylococcus aureus* known to cause inflammation in the retina. See column 3 lines 21-25, column 5 lines 36-42 and alternatively, see MOTLEY et al. page 203 Case Report, (describing redness and inflammation in posterior segment of the eye from *P. aeruginosa*). The hydrogel in example 2 has a water content of 60% and is composed of a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethacrylate, and methacrylic acid. See example 2, claims 7 and 11. The hydrogel can be a contact lens that is shaped and anionic. See claims 4, 8 and 9. The drug can further be released passively into the ocular environment. See claim 1.



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Thus, instant claims 1, 2, 3, 5, 6, 9, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by SCHULTZ.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over SCHULTZ (US 5,723,131) in view of SCHULTZ (US 2002/0197300) in view of AHLHEIM et al. (WO 03/024420) and in view of GERKOWICZ et al (1985).

Teachings of SCHULTZ ('131) are discussed above and are incorporated herein by reference.

SCHULTZ ('131) does not explicitly teach the use of VEGF antagonists as a drug in hydrogels, the passive release of a drug under ambient conditions, that the drug is capable of being delivered to the posterior segment of the eye, or that the contact lens

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has a base curve of 8.0 and 9.0 and can correct vision in the range of +8.0 to -8.0 diopters.

SCHULTZ ('300) describes a polymeric hydrogel that can absorb an ophthalmic medication that is transferred into the ocular fluid of the eye. See paragraph [0014]. The hydrogel has a water content of 10-90% or 38-60% by weight and can be ionic or non-ionic. See paragraph [0031]. Drugs capable of use in the hydrogel are antibiotics, cytokines, interleukins and anti-complement factors. See paragraph [0034]. The contact lens of '300 can correct vision in the range of +8.0 to -8.0 diopters with a base curve from 8.0 to 9.0. See paragraph [0031]. The passive release of a drug under ambient conditions is disclosed in claim 5.

AHLHEIM describes the use of a polymer containing an active for the treatment of ocular diseases. The drug is an anti-VEGF agent. See page 6 line 15 and line 20.

GERKOWICZ describes the use desferrioxamine to treat iron placed in the ocular orbit and sclera. While the penetrative ability of desferrioxamine to reach the posterior segment of the eye is relatively small it is still easily capable of reaching the retina, choroid or sclera demonstrating that desferrioxamine is capable of not only ameliorating symptoms in the anterior portion of the eye, but also the posterior segment of the eye See Figure 3, Figure 4 and page 104 second column first paragraph.

A motivation to combine the above elements is the ability to treat posterior segment disease by the use of contact lens, which at the same time corrects the subject's vision.

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Therefore, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice a polymeric hydrogel containing a drug capable of ameliorating or stabilizing a posterior segment disease, thus resulting in the practice of the instantly claimed invention with a reasonable degree of success.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-19 of copending Application No. 10/971997. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

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USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Instant claims 1-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 5, 9-13 and 16-20 of U.S. Patent No. 7,169,406 in view of SCHULTZ (US 6,410,045).

Instant claims 1-14 are directed to a hydrogel comprising a drug wherein the drug is capable of treating posterior segment disease. The drug can be a number of agents as listed in instant claims 3 and 4, e.g. anti-VEGF agents. The hydrogel has a water content of between 10% and 90% or between 37.5% and 75% and is composed of a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethacrylate, and methacrylic acid. The hydrogel can be a contact lens capable of correcting vision in the range of +8.0 to -8.0 diopters and has a base curve of 8.0 and 9.0. The drug is further capable of being passively delivered to the posterior segment of the eye or ocular environment.

Claims 1, 2, 4, 5, 9-13 and 16-20 of U.S. Patent No. 7,169,406 are directed to a hydrogel contact lens having a water content between 37.5% and 75% comprising an anti-inflammatory drug compound. The hydrogel further comprises a growth factor that

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can be substantially pure. The contact lens is capable of correcting vision in the range of +8.0 to -8.0 diopters and has a base curve of 8.0 and 9.0.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the term drug in the instant application encompasses an anti-inflammatory compound and one of ordinary skill would be motivated to substitute anti-inflammatory compounds for the anti-VEGFs of the instant invention when treating neovascularization of the posterior segment because, as stated in *AHLHEIM* above, anti-VEGFs are known to treat posterior segment diseases. *SCHULTZ* (US 6,410,045) column 2 lines 31-32 further states that the "use of conventional hydrogel contact lens containing various medications is known in the art" thus obviating the use of an anti-VEGF agent in the instant hydrogel contact lens.

Therefore, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the use of anti-VEGF agents in the instant hydrogel for the treatment of posterior segment diseases, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

Claims 1-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 30-34, 38-39, 47, 58 and 60-80 of copending Application No. 11/102454 in view of *SCHULTZ* (US 6,410,045).

Instant claims 1-14 are directed to a hydrogel comprising a drug wherein the drug is capable of treating posterior segment disease. The drug can be a number of agents as listed in instant claims 3 and 4, e.g. anti-VEGF agents. The hydrogel has a water

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content of between 10% and 90% or between 37.5% and 75% and is composed of a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethacrylate, and methacrylic acid. The hydrogel can be a contact lens capable of correcting vision in the range of +8.0 to -8.0 diopters and has a base curve of 8.0 and 9.0. The drug is further capable of being passively delivered to the posterior segment of the eye or ocular environment.

Claims 1, 30-34, 38-39, 47, 58 and 60-80 of copending Application No. 11/102454 are directed to an article comprising an anti-angiogenesis nucleic acid drug. The drug can be an anti-sense antagonist of VEGF and is transportable through the cornea or sclera or via the sinusal cavity. The contact lens is capable of correcting vision in the range of +8.0 to -8.0 diopters and has a base curve of 8.0 and 9.0. A method of treating posterior segment disease is disclosed using the said drug. The drug is further capable of being passively released from the article. The article is a hydrogel contact lens having a water content between 37.5% and 75% or between 10% and 90%. The article is capable of correcting vision and is composed of a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethacrylate, and methacrylic acid

Although the conflicting claims are not identical, they are not patentably distinct from each other because the term drug in the instant application encompasses anti-angiogenesis nucleic acid drugs and one of ordinary skill would be motivated to substitute anti-angiogenesis nucleic acid drugs for the anti-VEGFs of the instant invention when treating neovascularization of the posterior segment because, as stated in AHLHEIM above, anti-VEGFs are known to treat posterior segment diseases.

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SCHULTZ (US 6,410,045) column 2 lines 31-32 further states that the "use of conventional hydrogel contact lens containing various medications is known in the art" thus obviating the use of an anti-VEGF agent in the instant hydrogel contact lens.

Therefore, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the use of anti-VEGF agents in the instant hydrogel for the treatment of posterior segment diseases, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 8, 11, 12, 13, 14, 15 of copending Application No. 10/132843 in view of SCHULTZ (US 6,410,045).

Instant claims 1-14 are directed to a hydrogel comprising a drug wherein the drug is capable of treating posterior segment disease. The drug can be a number of agents as listed in instant claims 3 and 4, e.g. anti-VEGF agents. The hydrogel has a water content of between 10% and 90% or between 37.5% and 75% and is composed of a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethacrylate, and methacrylic acid. The hydrogel can be a contact lens capable of correcting vision in the range of +8.0 to -8.0 diopters and has a base curve of 8.0 and 9.0. The drug is further capable of being passively delivered to the posterior segment of the eye or ocular environment.

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Claims 1, 5, 8, 11, 12, 13, 14, 15 of copending Application No. 10/132843 are directed to a hydrogel contact lens comprising a substantially pure growth factor drug. The contact lens is capable of correcting vision in the range of +8.0 to -8.0 dipoters and has a base curve of 8.0 and 9.0. A method of treating posterior segment disease is disclosed using the said drug. The drug is further capable of being passively released from the contact lens into an ocular environment under ambient conditions. The contact lens is capable of correcting vision and is composed of a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethacrylate, and methacrylic acid

Although the conflicting claims are not identical, they are not patentably distinct from each other because the term drug in the instant application encompasses a substantially pure growth factor and one of ordinary skill would be motivated to substitute growth factors for the anti-VEGFs of the instant invention when treating posterior segment diseases because, as stated in AHLHEIM above, anti-VEGFs are known to treat posterior segment diseases. SCHULTZ (US 6,410,045) column 2 lines 31-32 further states that the "use of conventional hydrogel contact lens containing various medications is known in the art" thus obviating the use of an anti-VEGF agent in the instant hydrogel contact lens.

Therefore, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the use of anti-VEGF agents in the instant hydrogel for the treatment of posterior segment diseases, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.



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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tristan J. Mahyera whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TJM/

  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER